NATIONAL WOMEN'S HEALTH NETWORK

Prescription Drug User Fee Act (PDUFA) Meeting
FDA and Stakeholders Public Meeting

Comments of Cynthia Pearson
Executive Director

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Good morning. I'm very pleased to have the opportunity to provide input from the consumer advocacy community about the future of the Prescription Drug User Fee Act (PDUFA) program. I am the Executive Director of the National Women's Health Network, a national non-profit women's health advocacy organization which is supported by 10,000 individual members and 300 organizational members. The Network takes no contributions from pharmaceutical companies or from other entities with a financial stake in women's health care decision-making.

The Network always begins its statements at Food and Drug Administration (FDA) meetings by announcing that policy – that we do not receive any financial support from the pharmaceutical industry – so many of you who have heard us speak at meetings over the years may take it for granted that I would begin that way. Usually we open with the statement in order to comply with the FDA's disclosure requirements. But today, I did it for another reason.

That policy, which establishes our organization's financial autonomy from the companies and products on which we comment, reflects an important philosophical commitment of the National Women's Health Network. We believe that our independent decision-making as well as the high level of public confidence in our integrity and in the reliability of our analysis grow in large part from the clear line we are able to draw between ourselves and those entities which stand to profit or lose money from drugs and devices marketed to women.

Our greatest concerns about the PDUFA program relate to the ways in which we believe it has blurred that line for the FDA, undermining both the agency's independence and the public's confidence in the quality of consumer protection that it offers. Both the financial relationship that the use of PDUFA fees creates between industry and the agency and the consultative influence over the agency's decision-making process which the PDUFA legislation conferred to the industry have fundamentally changed the nature of the relationship between the FDA and the industry it is intended to regulate.

Financial conflict of interest

The PDUFA program has provided the FDA with funds which have made it possible to review human drug and biological products more quickly. If this could be done without compromising the quality and integrity of the agency's work, faster review would clearly be a benefit to consumers as well as industry. The structure of the PDUFA program, however, creates an inherent financial conflict of interest that at a minimum undermines public confidence in the agency and that appears to have in fact negatively affected the quality of the FDA drug review process.

The increasing dependence on fees paid by the regulated industry which the FDA itself describes in the Federal Register notice announcing this meeting is very troubling to those of us in the consumer advocacy community. Even while we serve as gadflies and critics of the FDA, we also view ourselves as colleagues and allies of the agency staff. The FDA is charged with safeguarding the public's health by ensuring public access to safe and effective drugs. We view our charge as monitoring and supporting the agency's efforts to achieve that goal. Although we

are very interested in expanding the resources available to the agency to accomplish its work, funds which make the agency dependent on the industry it is regulating and which come with strings attached do not truly expand the resources available for the kind of independent, regulatory action that the public expects and needs from the FDA.

Industry influence over performance goals

Under the PDUFA program, the FDA agreed to meet a set of performance goals which were established in consultation with industry and without any consultation with consumers. These goals bound the agency to a specific timeline for review of drug and biological product applications. As consumer advocates, we have several concerns about this situation. First, the establishment of timelines to be applied to all drugs and biologics, regardless of the varying review needs associated with a specific product diminishes the agency's ability to conduct appropriate and sufficient reviews.

Second, the inflexibility of the deadlines creates an opening for sponsors to use time pressure to limit the thoroughness of the agency's review. By waiting until late in the process to provide the agency with required data, sponsors have been able to restrict the amount of time that FDA staff has to review information. In the case of the approval of tamoxifen for reduction of breast cancer risk, the sponsor provided some data so late that FDA staff were not able to conduct a full analysis of the data prior to the advisory committee meeting to consider the application; additionally, there was some data that had been requested which had still not been provided by the time of the meeting when a recommendation was made. This meant the agency went forward with a decision based on a recommendation that was made without complete information and without a full analysis of even the available data.

Finally, we strongly object to the consultative role in establishing the performance goals which PDUFA conferred on industry. It is inappropriate and counter to the goals of consumer protection to accord a regulated industry the authority to establish performance goals for its regulator. FDA's oversight of drug safety and effectiveness cannot help but be undermined by industry's influence over the regulatory process. On the other hand, it would be entirely appropriate to consult with consumers in establishing performance goals for an agency charged with consumer protection – yet this is not required under PDUFA.

Conclusion

In summary, the National Women's Health Network believes that the financial conflict of interest and industry influence over the drug and biologics approval process created by PDUFA have had a detrimental effect on the quality of the FDA review and approval process. Funding the FDA fully through federal revenue would be preferable since it would eliminate the conflict and inappropriate influence. If industry fees are going to continue to be a revenue source for the agency, we urge the FDA advocate for amendments which will address these problems. First, the financial conflict of interest must be addressed by disassociating the fees from any particular function of the agency. And second, any performance goals must be established in consultation with consumers, independent of influence by the regulated industry.